IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/795,830	Confirmation No.: 2799
Applicant	:	James E. Grimm et al.	
Filed	:	March 8, 2004	
Title	:	NAVIGATED ORTHOPAEDIC GUIDE AND METHOD	
TC/A.U.	:	3733	
Examiner	:	Michael B. Priddy	
Docket No.	:	ZIM0417 (ZM0618)	
Customer No.	:	43963	

Commissioner for Patents
P.O. Box 1450
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DECLARATION UNDER 37 C.F.R. § 1.131
OF JAMES E. GRIMM AND SHAWN E. MCGINLEY

We, James E. Grimm and Shawn E. McGinley, inventors of the invention disclosed and claimed in Claims 2-4, 8-10, 15-19, 21-23 and 25-26 of the above-identified patent application, hereby declare as follows:

1. That the Examiner in U.S. Patent Application Serial No. 10/795,830 (hereinafter "the present application") rejected Claims 2-4, 8-10, 15-19, 21, 23 and 25 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0039396 to Couture et al. (hereinafter "Couture et al. '396").
2. That Couture et al. '396 was filed on February 4, 2003 and claims priority to U.S. Provisional Patent Application No. 60/405,326, filed on August 23, 2002.
3. That prior to August 23, 2002, we constructed and used a surgical instrument in the United States of America in accordance with the claims of the present application. Figure A attached hereto is a picture taken prior to August 23, 2002, of an exemplary embodiment device constructed prior to August 23, 2002, which generally corresponds to Figures 1-3 of U.S. Patent Application Serial No. 10/325,088, from which the present application claims priority and Figure B attached hereto is a model representation created prior to August 23, 2002, of an exemplary embodiment device

constructed prior to August 23, 2002, which generally corresponds to Figures 4 and 5 of U.S. Patent Application Serial No. 10/325,088, from which the present application claims priority. Figures C1-C3 are pictures of an exemplary embodiment device corresponding to a device constructed prior to August 23, 2002 and which generally correspond to Figures 1-3 and 7 of U.S. Patent Application Serial No. 10/325,088, from which the present application claims priority. Appendix D1-D3 attached hereto is a claim chart correlating Claims 2-4, 8-10, 15-19, 21-23 and 25-26 to Figures A, B and C1-C13. Referring to Figures A, B and C1-C13, an exemplary surgical system for use during an orthopaedic surgical procedure is shown in accordance with the pending claims of the present application. The device shown in Figures A, B and C1-C13 attached hereto was constructed and used with a surgical navigation system including means for tracking the position of an object during a surgical procedure, comprising multiple sensors to detect and triangulate the position of the orthopaedic guide. Referring specifically to Figure B, means for being tracked by the surgical navigation system to guide positioning of the orthopaedic guide is shown. The device shown in Figure B may be equipped with any reference element technology, such as optical tracking technology, radiofrequency tracking technology, and electromagnetic tracking technology, for example. Moreover, the device shown in Figure B is mountable to the instrument body shown in Figure A and Figures C1-C5 (identified with reference numeral 10).

4. That the surgical instrument constructed in accordance with the claims of the present application operated according to its intended purpose prior to August 23, 2002.

5. We hereby declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements, and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the present application or any patent issuing thereon.

Date: MARCH 28, 2008 By: James E. Grimm
James E. Grimm

Date: MARCH 28, 2008 By: Shawn E. McGinley
Shawn E. McGinley

FIGURE A

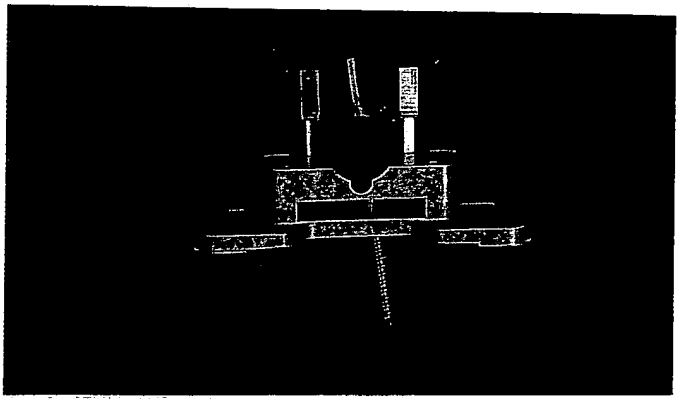
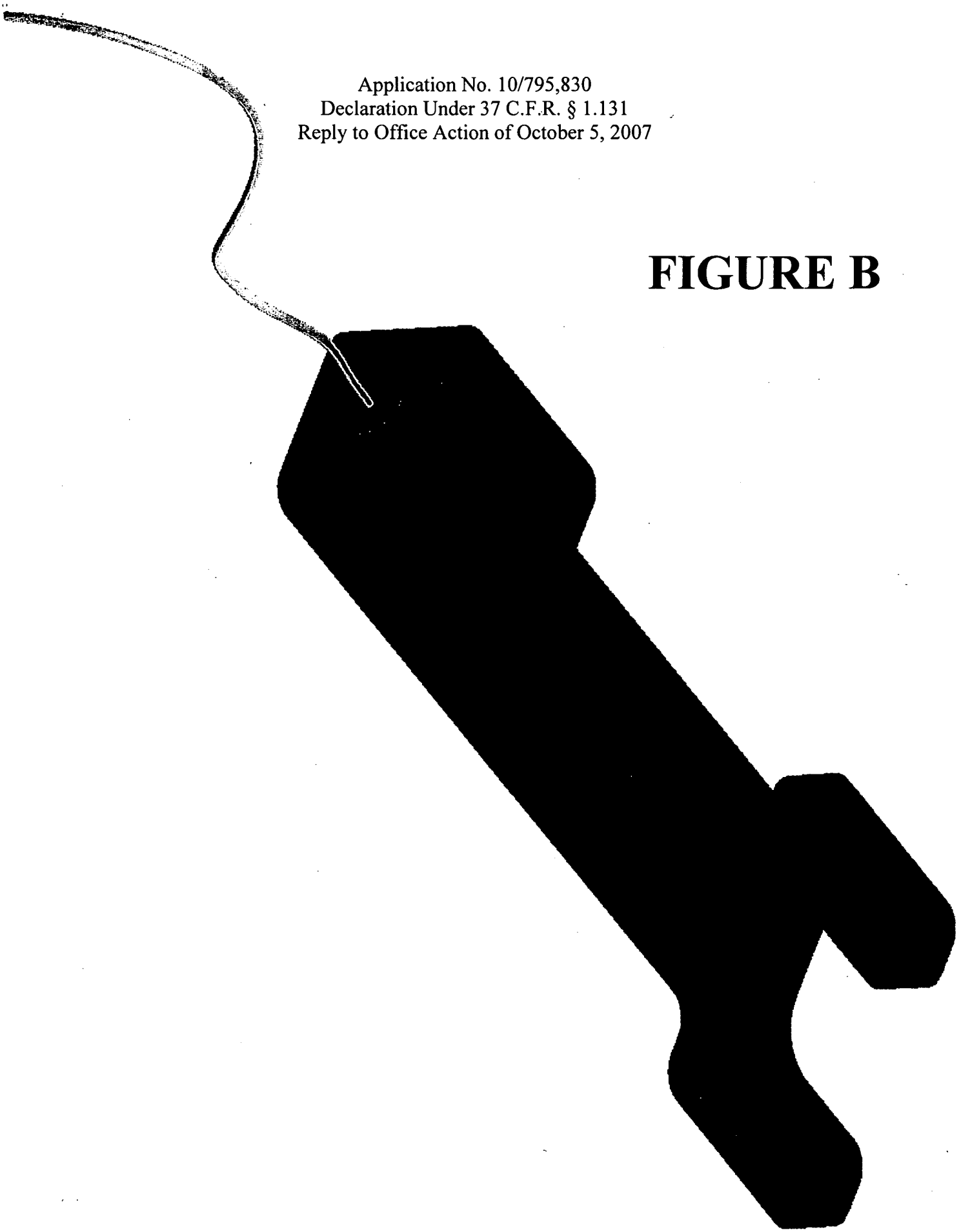
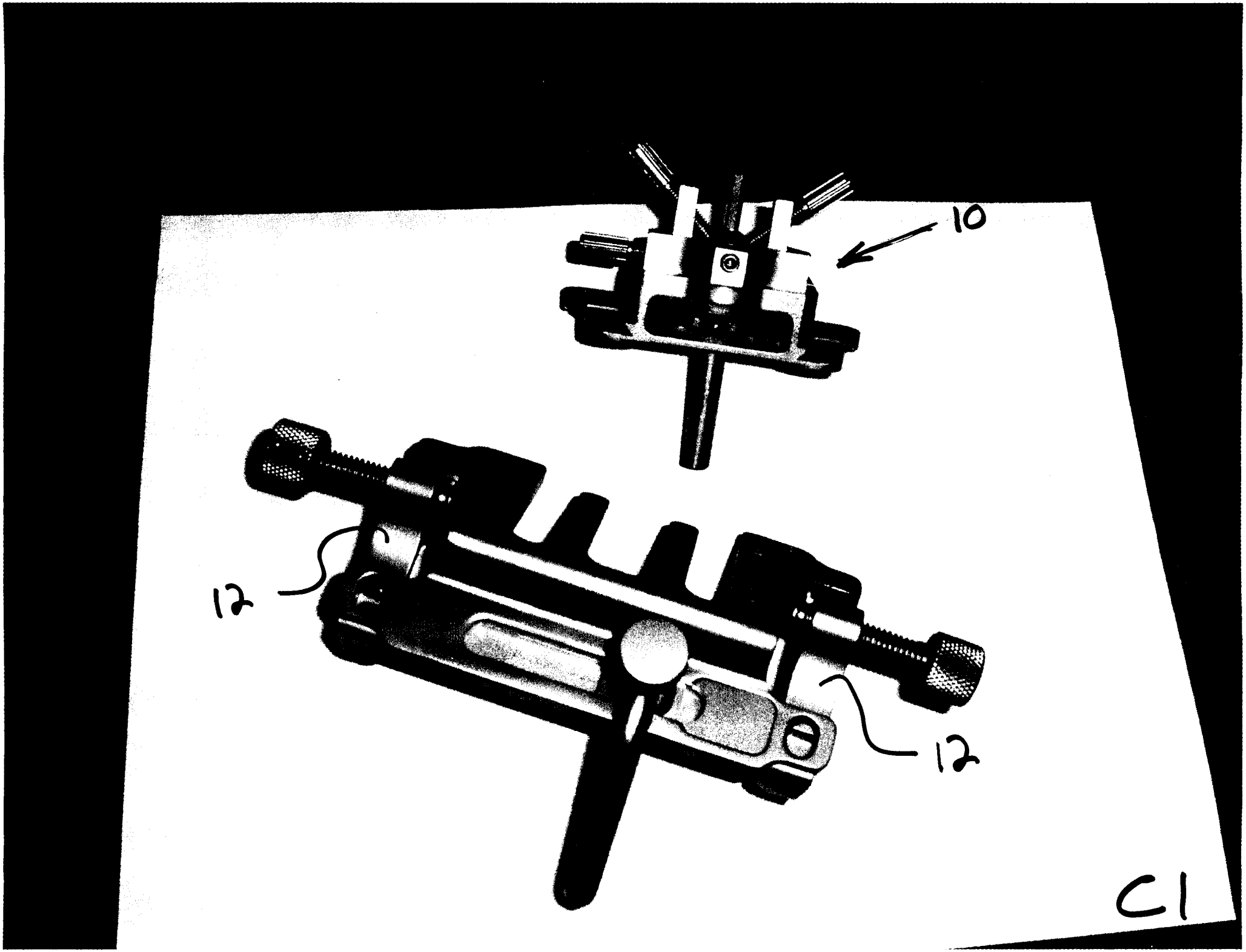


FIGURE B



C1 – C13


10
12
12
C1

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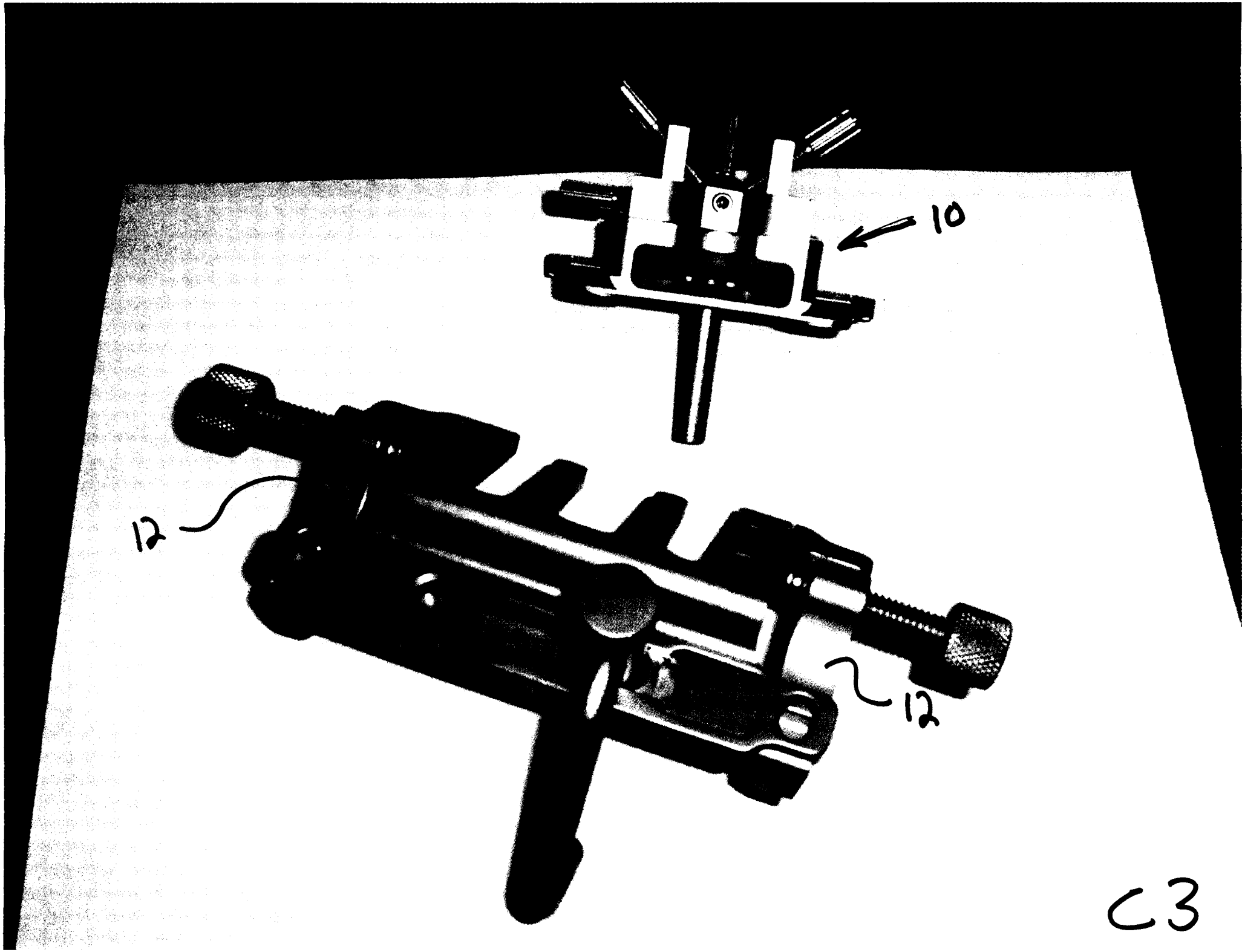
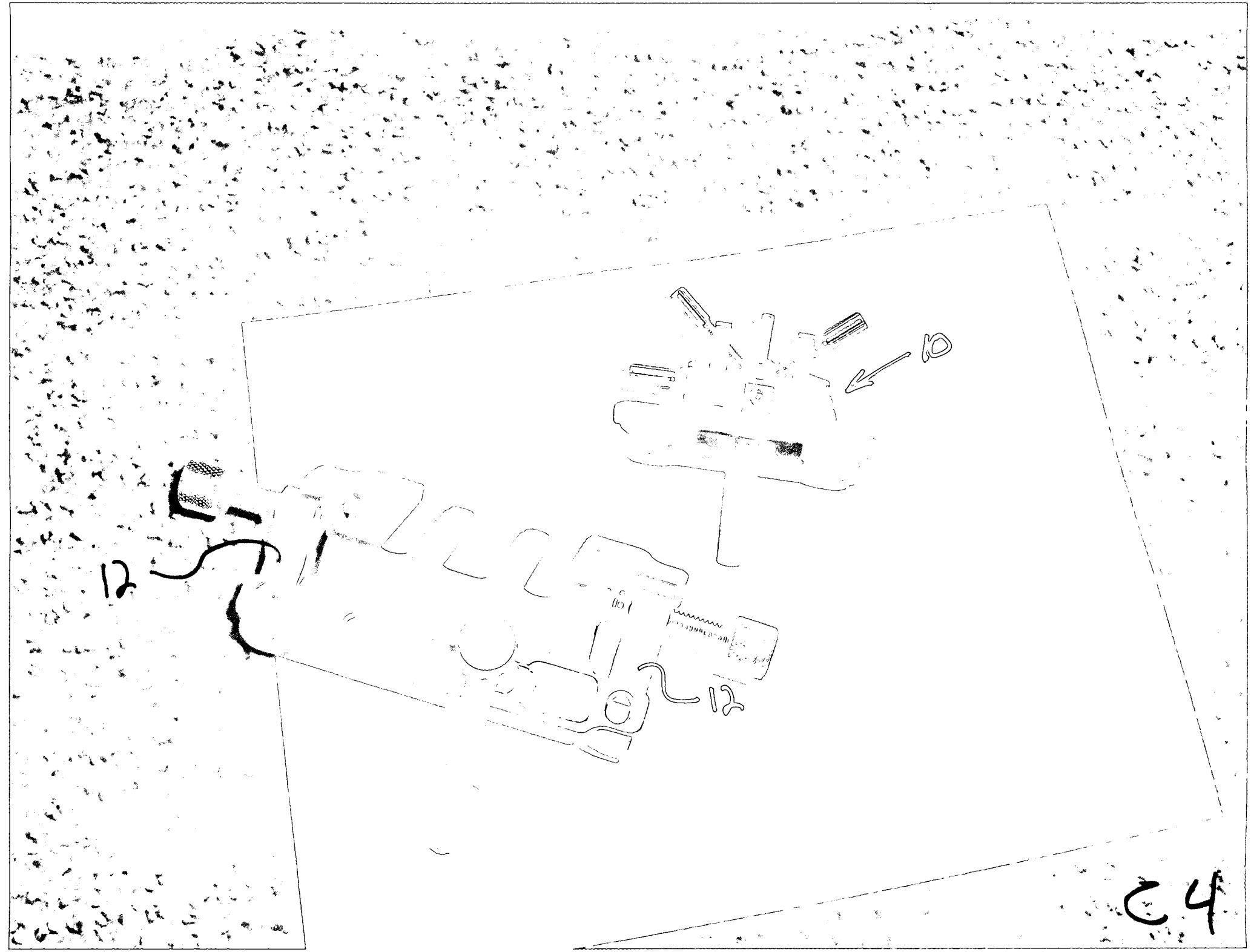
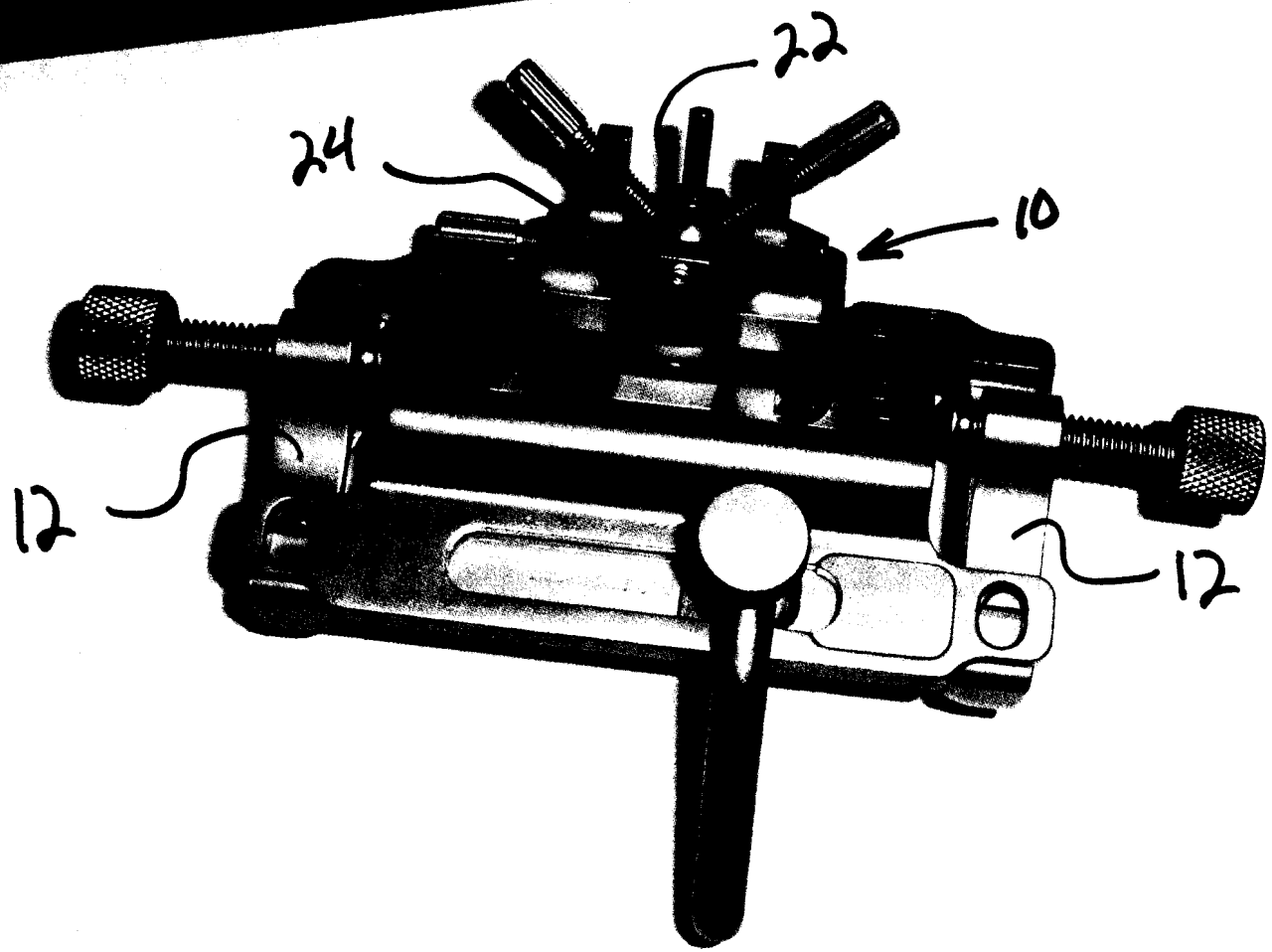


C3



C4


22
24
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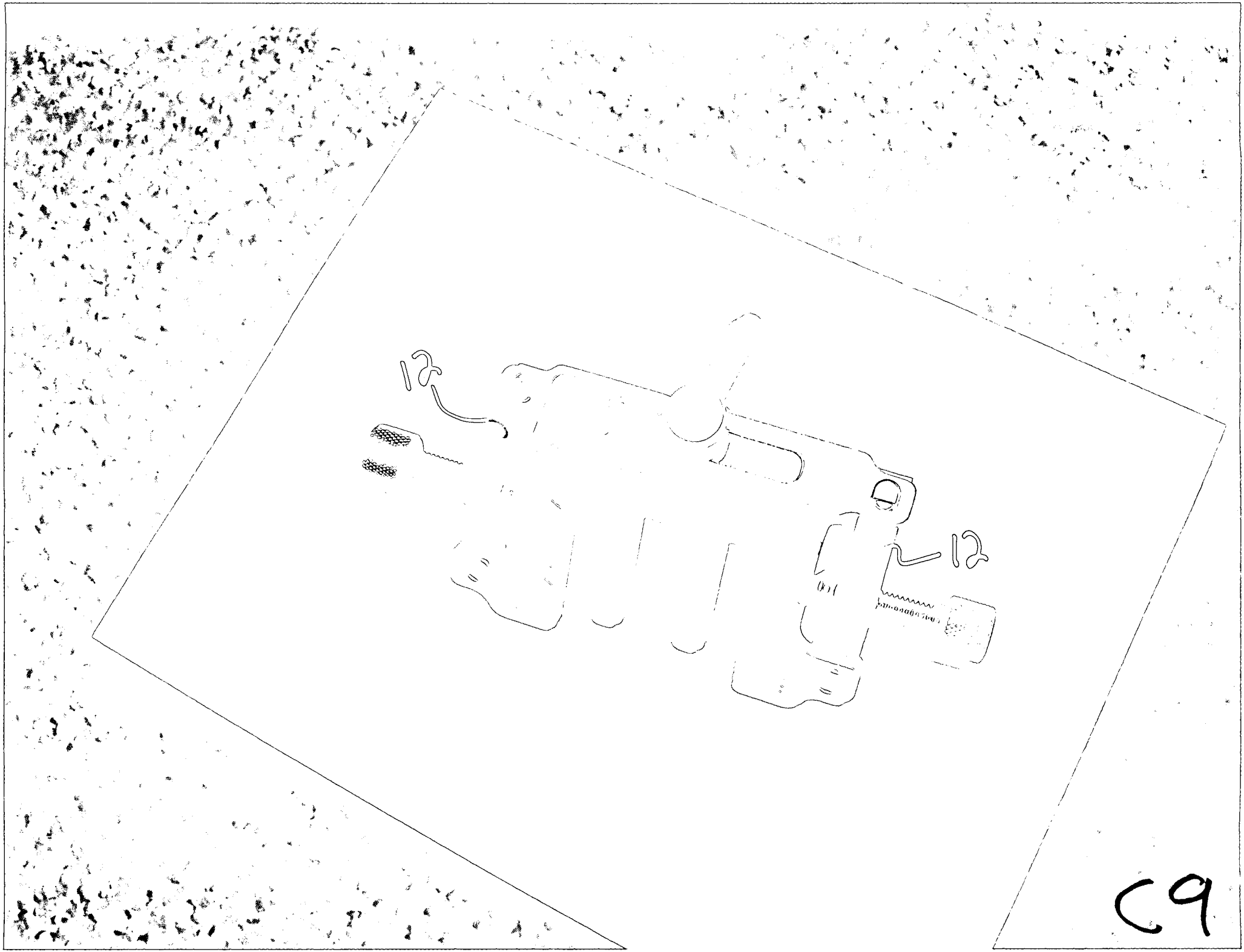
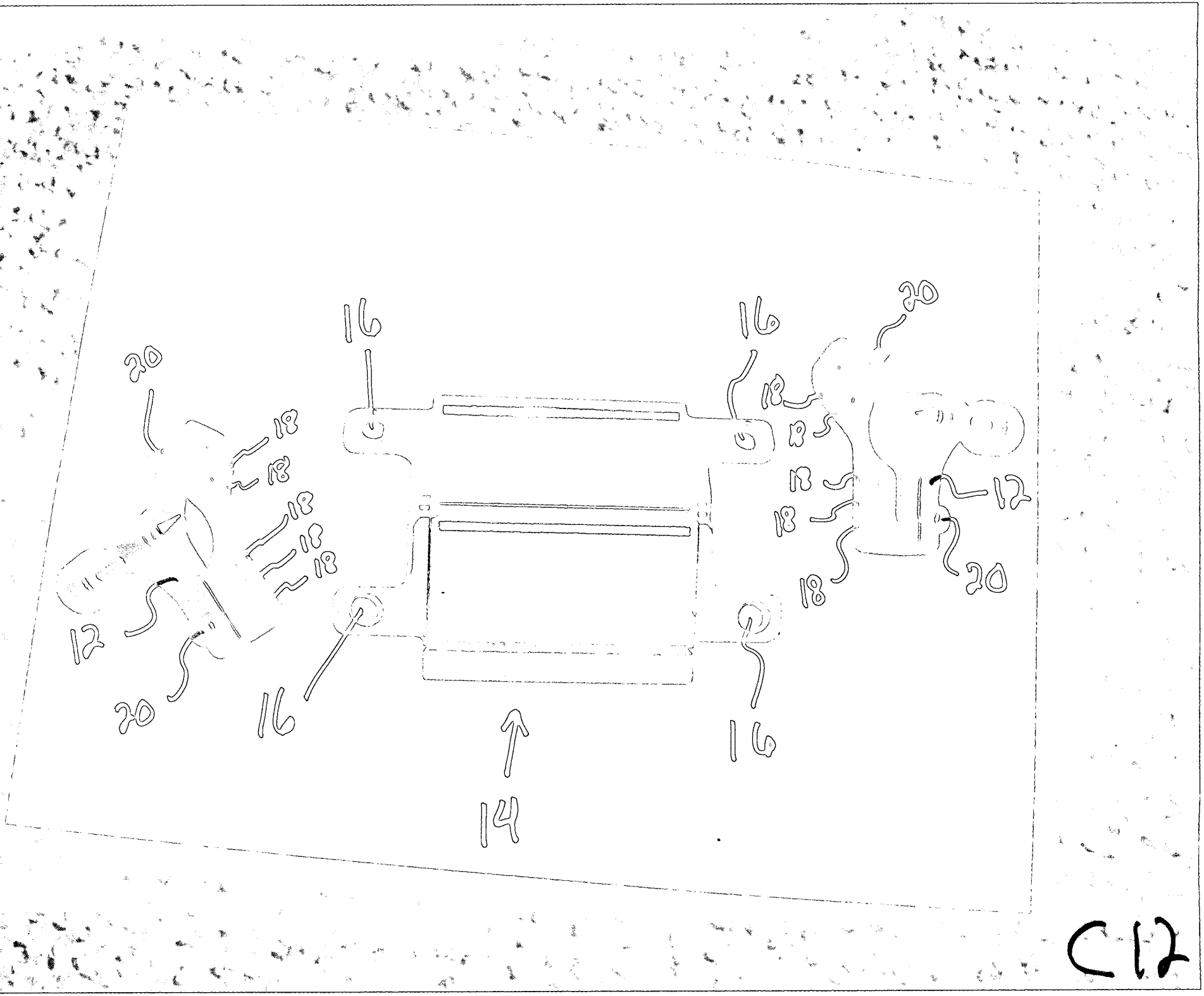
12



C9



C12

C13

D1 – D3

NAVIGATED ORTHOPAEDIC GUIDE AND METHOD ZIM0417	
CLAIMS OF 10/795,830	
2. The surgical system of claim 15 wherein the means for establishing a datum comprises means for establishing one or more datums relative to the surgical site selected from the list consisting of pins, screws, bars, fins, rails, dovetails, planar surfaces, holes, slots, and/or notches.	means for establishing a datum (12)
3. The surgical system of claim 15 wherein the means for establishing a datum comprises means for establishing an intermediate datum separate from the guide itself.	means for establishing a datum (12) is separate from guide (14)
4. The surgical system of claim 15 wherein the means for establishing a datum comprises a guide body including a plurality of holes through the body for guiding the placement of pins relative to the surgical site.	means for establishing a datum (12) comprising holes (18)
8. The surgical system of claim 15 wherein the means for establishing a datum includes a base member and a datum guide member connected to the base member such that the position of the datum guide member is adjustable relative to the base member to a desired datum guide member position as indicated by the surgical navigation system.	base member 22 and datum guide member 24
9. The surgical system of claim 8 wherein the base member is able to be secured to a distal portion of a femur and the datum guide member is adjustable relative to the base member to establish a datum having desired flexion-extension and varus-valgus angles as indicated by the surgical navigation system.	base member 22 and datum guide member 24
10. The surgical system of claim 8 wherein the base member is able to be secured to a proximal portion of a tibia and the datum guide member is adjustable relative to the base member to establish a datum having desired posterior slope and varus-valgus angles as indicated by the surgical navigation system.	base member 22 and datum guide member 24
15. A surgical system for use during an orthopaedic surgical procedure at a surgical site of a patient's body, the system comprising:	
a surgical navigation system including means	see 131 declaration paragraph 3.

for tracking the position of an object during a surgical procedure;	
a navigated orthopaedic guide including means for being tracked by the surgical navigation system to guide positioning of the orthopaedic guide at a desired position relative to the surgical site, the orthopaedic guide including means for establishing a datum at a desired position relative to the surgical site; and	navigated orthopaedic guide (10) including means for being tracked by the surgical navigation system (Figure B) . . . the orthopaedic guide including means for establishing a datum at a desired position relative to the surgical site (12)
a surgical component including means for engaging the datum positioned by the orthopaedic guide to locate the surgical component at a desired position relative to the surgical site.	surgical component (14) including means (16 – see Figure C12) for engaging the datum (12) positioned by the orthopaedic guide to locate the surgical component at a desired position relative to the surgical site
16. The system of claim 15 wherein the means for tracking comprises multiple sensors to detect and triangulate the position of the orthopaedic guide.	see 131 declaration paragraph 3
17. The system of claim 15 wherein the means for being tracked comprises an electromagnetic coil attached to the orthopaedic guide, the electromagnetic coil producing a signal detectable by the means for tracking.	see 131 declaration paragraph 3
18. The system of claim 15 wherein the means for establishing a datum comprises a drill guide to guide a drill in forming a hole in a bone at the surgical site	drill guides (18)
19. The system of claim 15 wherein the means for establishing a datum comprises at least one hole in the orthopaedic guide to guide placement of a pin adjacent the surgical site.	means for establishing a datum (12) comprising holes (18)
21. The system of claim 15 wherein the surgical component comprises a cut guide to guide a cutter to cut a bone to receive an implant.	surgical component (14) comprises a cut guide having cut slots
22. The system of claim 21 wherein the cut guide comprises a femoral finishing guide including guides for guiding a saw blade to shape the end of a femoral bone to receive a femoral knee implant.	surgical component (14) comprises a femoral finishing guide including guides for guiding a saw blade to shape the end of a femoral bone to receive a femoral knee implant
23. The system of claim 21 wherein the cut guide comprises a distal femoral cut guide.	surgical component (14) comprises a distal femoral cut guide
25. The system of claim 15 wherein the means for engaging the datum comprises at least one hole formed in the surgical component to	means for engaging the datum (12) comprises at least one hole (16 – see Figure C12) formed in surgical component (14) to receive datum

receive the datum in the form of a pin.	pins 20
26. The system of claim 15 wherein the means for establishing a datum directly engages the subsequent surgical component.	means for establishing a datum (12) directly engages guide (14)